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## Standards Working Group Meeting

2016 Annual Meeting of the  
Scientific and Medical Accountability Standards Working Group  
of The California Institute For Regenerative Medicine  
Organized Pursuant To The  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

Date: Thursday February 4, 2016

### CIRM Scientific and Medical Accountability Standards Working Group Workshop on Human Gene Editing

*This workshop took place on February 4, 2016*

*[Click here to listen to an audio recording of the workshop \[5 hours 47 minutes\]](#)*

#### Background:

A series of science-policy initiatives have been undertaken to address the use of human genome editing technologies in biomedical research. These initiatives include:

- The International Summit on Human Gene Editing
- The National Academy of Sciences and the National Academy of Medicine's Human Gene-editing Initiative
- The Draft ISSCR Guidelines for Stem Cell Science and Clinical Translation

These initiatives have sought to develop a framework for the application of human genome editing in biomedical research. Given these science-policy deliberations, CIRM will review its policies governing the funding and oversight of research involving human genome editing.

#### Scientific & Policy Context:

Understanding the biology of human embryos and germ line cells has been identified as a basic and pre-clinical research imperative provided protocols are subject to effective oversight. CIRM has the unique ability to fund research involving human embryos and gametes. CIRM's Medical and Ethical Standards provide a comprehensive framework for the review and oversight of embryo and gamete research under the auspices of a Stem Cell Research Oversight Committee. Under this framework, CIRM-funded researchers have made important scientific contributions including the derivation of new hESC lines and insights into human development and the disease process.

#### Charge:

Pursuant to its mission, CIRM will continue to support groundbreaking stem cell treatments and technologies, including gamete and embryo research, from their inception to translation. In light of recent science-policy initiatives, the Scientific and Medical Accountability Standards Working Group is, specifically, being asked to review CIRM policies associated with gene editing of human germ cells and embryos. One objective of this review is to ensure CIRM research continues to be conducted under the highest medical and ethical standards.

#### Agenda (Subject to Change):

1. Review of International Summit recommendations: David Baltimore

Provide a summary of the International Summit Statement with an emphasis on recommendations relating to gene editing of human gametes and embryos.

2. Review of ISSCR Guidelines: Jonathan Kimmelman

Provide a summary of the ISSCR Guidelines with an emphasis on recommendations relating to the review and oversight of studies involving gene editing human gametes and embryos.

3. National Academies' Human Gene Editing Initiative: Alta Charo

4. Review of current CIRM policy: CIRM Team

Describe CIRM requirements for the review and oversight of gamete and embryo research and consider how these requirements align with International Summit and ISSCR recommendations.

5. Research directions in California: Invited California Researchers: Amander Clarke, Jacob Corn, Juan Carlos Belmonte

Describe current and possible research involving human genome editing that CIRM may be asked to support.

6. Considerations for CIRM Governance & Oversight of research involving human genome editing: Henry Greely, Charis Thompson

Reflect on CIRM's policies for scientific review and research oversight in light of its mission, International Summit and ISSCR recommendations for research involving human gene editing, research directions in California, and ethical considerations.

7. Public comments

8. Discussion / deliberations: Standards Working Group & guest participants

Consider the adequacy of the CIRM policy framework in light of recent policy developments and emerging science.

9. Public comments

**THE ORDER OF BUSINESS MAY BE CHANGED WITHOUT NOTICE.**

**Additional Background Documents:**

- *Editing policy to fit the genome?*
- *A prudent path forward for genomic engineering and germline gene modification*
- *International Summit Statement on Genome Editing*
- *Draft ISSCR Guidelines*
- *CIRM Medical and Ethical Standards Regulations*
- *January 31, 2006 Standards Working Group Discussion on Genetically Modified Embryos*
- *UK Scientist Gain License to Edit Genes in Human Embryos*

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Questions or requests for additional information prior to the Scientific and Medical Research Funding Working Group meeting may be referred Geoffrey Lomax at the California Institute for Regenerative Medicine [glomax@cirm.ca.gov](mailto:glomax@cirm.ca.gov) or (510) 340-9146.

This meeting agenda is also available on the website for the California Institute for Regenerative Medicine at <http://www.cirm.ca.gov>.

**Transcripts:**



StdsWkgGroup-2-4-16 Transcript.pdf

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